



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 2/02, A61L 27/00	A1	(11) International Publication Number: WO 92/21302 (43) International Publication Date: 10 December 1992 (10.12.92)
(21) International Application Number: PCT/SE92/00366 (22) International Filing Date: 29 May 1992 (29.05.92) (30) Priority data: 9101677-4 3 June 1991 (03.06.91) SE (71) Applicant (for all designated States except US): LUCOCER AKTIEBOLAG [SE/SE]; Aurorum 1, S-951 75 Luleå (SE). (72) Inventor; and (75) Inventor/Applicant (for US only) : JOHANSSON, Thomas [SE/SE]; Lars Pähls väg 28, S-263 52 Höganäs (SE). (74) Agent: HYNELL, Magnus; Hynell Patenttjänst AB, Box 2236, S-683 02 Hagfors (SE).		(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (Eu- ropean patent), GN (OAPI patent), GR (European pa- tent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (Euro- pean patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US. Published <i>With international search report.</i>
(54) Title: AN IMPLANT (57) Abstract <p>The present invention relates to an implant made of a porous non-toxic material with a total open porosity larger than 5 percent by volume but not larger than 80 percent by volume within at least a portion of the implant. The implant is characterized in that: communicating pores with a pore size within the interval of 0.1-10 µm occupy 10-80 percent of the total pore volume in said at least one portion of the implant; pores with a pore size within the interval of 10-50 µm occupy not more than 5 % of the total pore volume in said at least one portion of the implant; and 5-40 % of at least one portion of the surface of the implant is covered by mainly evenly distributed pores having a pore size within the interval of 50-500 µm.</p> <div data-bbox="1079 1123 1404 1911" data-label="Image"> </div>		

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An implant

The present invention relates to the field of chiefly medical applications, more specifically to the field of implantology, and relates to an implant made of a porous, not toxic material having a total open porosity of more than 5 percent by volume but not more than 80 percent by volume within at least a portion of the implant.

BACKGROUND ART

In materials selected to be used in various types of supporting implants a minimum of pores, particularly large pores, is desirable as far as the strength is concerned. However, pores are also required, which are designed to allow a generally favorable situation for bone ingrowth and/or tissue ingrowth with an integrated interaction of soft and hard tissues. Pores can also be used as reservoirs for soluble substances, deposited in the material and having specific, often medical/biological functions. Examples are deposited substances, which function as a calcium or phosphorus source, containing bone growth factors or containing prophylactic or anti-inflammatory agents. The porosity then can be an excellent space for slow-release processes.

Hence, in spite of the strength reducing effect of the porosity, porous materials are used in implant techniques. However, for many materials the introduction of pores results in a dramatic strength reduction of the implant. This is particularly true in brittle materials having a low fracture strength. Fracture mechanical correlations indicate the size of the strength reduction for such materials with the following expression of fracture strength for such materials, also called the critical tension intensity factor ($\text{MPam}^{1/2}$):

$$K_{IC} = Y \sigma_f c^{1/2}, \quad (1)$$

in which Y is a geometric position and shape factor, σ_f is the fracture strength and c indicate the highest allowable defect.

In conventional materials for implant applications, e.g. aluminum oxide and hydroxyl apatite having fracture strength values of 3.0 and 1.0 $\text{MPam}^{1/2}$ respectively, e.g. a pore having a size of 200 μm results

in a maximum strength level about 150 and 40 MPa respectively, which implies that these two implant materials are questionable in mechanically highly stressed applications. There is also a risk that a slow fracture growth will occur, particularly for hydroxyl apatite, which means that tolerable stresses may very well be lower than the stated values.

New construction cerams, e.g. based on silicon nitride or zirconium oxide, are more suitable for such highly stressed applications. A ceramic material, which is able to retain a relatively high strength despite the presence of a large amount of pores, is reaction bound silicon nitride, Si_3N_4 (RBSN). However, also in these construction cerams as well as in other feasible implant materials, such as steel, titanium and other metals, polymers as well as in other oxidized or non-oxidized cerams, a balance must be attained between on the one hand the porosity and the properties of the pores and on the other hand the strength requirement.

BRIEF DISCLOSURE OF THE INVENTION

The object of the present invention is to provide an implant of the type set forth in the preamble, which is able to combine a high strength and a capacity to meet high requirements as to a favorable situation for bone ingrowth as well as tissue ingrowth with an integrated interaction between soft and hard tissues, as well as to provide reservoirs for substances to be deposited in the material and having specific functions. These and other objects can be attained according to the present invention by meeting the following requirements: communicating pores having a pore size of 0.1-10 μm are to occupy 10-80 % of the total pore volume of said at least one portion of the material; pores having a pore size of 10-50 μm are to occupy not more than 5 % of the total pore volume of said portion of the material; and 5-40 % of the surface of said least one portion of the implant is to be covered by mainly evenly distributed pores having a pore size of 50-500 μm .

Preferably said communicating pores with a pore size of 0.1-10 μm occupy 25-75 %, suitably 40-60 %, of the total pore volume in said at least one portion of the implant material.

- 5 Preferably the main part, calculated as to the volume, of the above-mentioned communicating pores have a pore size of 0.3-8 μm , suitably 0.5-5 μm .

- 10 Preferably 10-30 %, suitably 15-25 % of the surface within said at least one portion of the implant is covered by the mainly evenly distributed pores having a pore size of 50-500 μm .

The main part of the large pores in the surface layer preferably have a size of 75-400 μm , better 100-300 μm and best of all 150-250 μm .

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The large pores exist, according to one embodiment, only in a surface layer of the implant, namely a surface layer, which has a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm.

- 20 Although the material mainly has nil - or at least contains only a minor amount of - pores of 10-50 μm , large pores may nevertheless, provided the strength requirements are moderate, according to another embodiment of the invention exist in the interior of the material. According to this aspect of the invention larger pores with a pore
25 size of 50-500 μm , preferably 75-400 μm , more suitably 100-300 μm and best of all 150-250 μm occupy 10-80 % of the total pore volume.

- Pore size is defined, as regards pores with pore sizes which are less than or is equal to 50 μm , as sizes determined by means of conven-
30 tional Hg-porosimetry, the ratio between pore diameter (2r) being calculated by the formula:

$$p = \frac{2 s \cos F}{r}, \text{ in which}$$

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p = the pressure

s = the surface tension of Hg at the used temperature

F = meniscus angle (edge angle)

(reference: L.C. Ritter och R.L. Drake, Ind. Eng. Chem.

17 782 (1945).)

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Pore sizes, which are larger than 50 μm , are defined as sizes obtained through an optical determination in a light microscope on a cross-section of the test specimens, in a cut made 0.1 μm below the surface and in a cut transversely to the test specimen surface respectively. Also, the expression "the total pore volume in the material" is defined as that pore volume, which is measured through a water penetration.

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Thus, the present invention is characterized by complicated pore size distributions, which will allow optimal combinations of strength and soft tissue-formations as well as a favorable bone ingrowth.

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The large pores generally are conducive to bone ingrowth, whereas the small pores are conducive to soft tissue-formations, but the latter pores can also act as reservoirs for soluble substances, deposited in the material and having specific medical/biological functions. In order to allow a favorable bone ingrowth and a soft tissue-formation respectively the large as well as the small pores must be present in the surface of the implant, at least in a portion of the surface, in which it is desirable that said functions are to be active. Also, throughout the entire material the small pores belong to a communicating pore system, designed to act as said reservoirs for deposited substances, e.g. substances which contain calcium and/or PO_4 , preferably in the form of a calcium phosphate material, e.g. hydroxyl apatite, bone growth stimulating hormones, anti-inflammatory agents etc.

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The implant is made, according to the present invention, of powders, which are consolidated to a porous body, which process can be done according to any method known per se, e.g. a conventional sintering, .

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a cold pressing and subsequently a hot isostatic pressing or through nitridizing or the like. Thus, e.g. a material consisting of silicon nitride preferably is made by nitridizing silicon grains, a so called reaction bound silicon nitride (RBSN), Si_3N_4 being obtained. The material can also contain other substances than Si_3N_4 , but if Si_3N_4 is chosen, this material ought to be present in an amount of at least 80 percent by weight. Other feasible materials are calcium phosphate materials, e.g. hydroxyl apatite, Al_2O_3 , titanium, SiC , ZrO_2 , chromium, cobalt steel, high-alloy stainless steels, and certain polymers. The implant can completely consist of any of these materials or of mixtures of two or several of these materials or mainly consist of any of these materials in combination with some additional materials, not mentioned in this text. Also, it ought to be mentioned, that the implant can have a different composition in different parts, one part being porous according to the invention, whereas another part consists of a more conventional material and is essentially pore-free. Combinations of portions having different compositions but each one of the portions being porous according to the inventive idea are also feasible.

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The porosity and the pore size distribution of the material can be controlled by means of any or several of the following methods:

- 1) through a selection of the original grain size of the raw material;
- 2) through a regulation of process parameters, pressure, temperature and time during the consolidation (densification);
- 3) through admixtures to gases or to the raw material; and
- 4) through a final treatment.

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Thus, the finer pore fraction is obtained by controlling 1) and 2) above. Regarding an RBSN-material, e.g. the size of the original Si-grains is decisive for the pore size of the fine pore fraction and its distribution in a formed reaction bound silicon nitride (RBSN), whereas the larger pores in the surface preferably are obtained through the final treatment according to 4) above. In case it is desirable, instead or in combination with larger pores obtained through a final treatment of the surface, to also obtain larger pores in the main part of the material, this can be done by an admixture in

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the raw material of fibers, e.g. of a polymer, a ceramic or a metal, which are burned off or leached off before or after the consolidation of the material. Also, glass fibers can be added, which can be used as sintering agents or be removed before or after the consolidation. In order to obtain the larger pores in the surface layer a laser process and/or an ultrasound process or a water jet cutting process are particularly useful. In this way pores having a particularly favorable pore profile can be obtained, which reduces the tension concentrations around the pores. When using such a technique, which means that not only a pore size and a pore depth are chosen but also a pore profile, the implant material can be stressed more than before, the Y -value in the rupture mechanical basis formula $K_{IC} = Y \sigma c^{1/2}$ being lowered from the theoretical maximum value of 1.98 to about 1.2-1.4.

As regards materials, obtained by consolidating powders of various metals or very resistant ceramic materials, combinations of a fine porosity and a coarse (macro-) porosity can be obtained through some sintering process, which is not completed and is followed by a surface treatment, e.g. through some of the techniques described above, in order to obtain a macrosurface porosity. Interesting materials are Co-Cr-steels, Ti-alloys and ceramics, primarily oxides of aluminum and zirconium as well as non-oxidic materials of silicon nitride- and SiALON-type.

Additional characterizing features and aspects of the present invention are set forth in the following examples and the enclosed patent claims.

BRIEF DESCRIPTION OF DRAWINGS

In the following description reference will be made to the accompanying drawings, in which:

Fig. 1 shows a shoulder prosthesis with a portion consisting of a porous material according to the invention;

Fig. 2 shows a hip joint prosthesis, in which also a portion consists of a porous material according to the invention;

Fig. 3 shows a dental implant, designed to fasten teeth in a bone,

which implant also has a porous portion according to the invention;
Fig. 4-7 schematically show how surface macropores present in the
material may be designed; and
Fig. 8 is a diagram, which shows the transverse force required to
5 discharge an implant as a function of the ingrowth time.

DESCRIPTION OF EMBODIMENTS

Example 1

Fibers consisting of pieces, 1-2 mm, of a nylon cord having a diameter
10 of 0.2 mm are added to a powder mixture comprising zirconium oxide and
3 percent by volume yttrium oxide. The amount of fibers is 12 percent
by volume. The mixture is tumbled for 2 hours in a roller-type ball
mill with a polymer container and spherical crushing balls made of
zirconium oxide. Raw compacts are made through cold pressing at a
15 pressure of 250 MPa. The raw compacts are heat treated in order to
evaporate the organic component, i.e. the nylon fibers. The evapora-
tion is done by elevating the temperature 5°C/hour up to 500°C. The
relatively brittle raw compact which is obtained is sintered at 1550°C
for 3 h. Hg-porosimetry shows pores with a size of about 1 µm. An
20 optical examination in a light microscope of a cross-section shows a
presence of large pores with a size of about 170 µm.

Example 2

An aluminum oxide powder of a grade called AKP 30, having a specific
25 surface (BET) of about 20 m²/g, which corresponds to a grain size of
less than 0.1 µm, is compressed to a cubic specimen with the dimen-
sions 10 x 10 x 10 mm. The specimen, encased in glass, is densified by
means of a hot isostatic pressing, a so called HIP-ing. The densifica-
tion (compression) is done at 1150°C for 20 min. The maximum pressure
30 at the highest temperature is 160 MPa. The porosity is measured
through a water penetration and is 14.5 percent by volume. Hg-
porosimetry shows that the main part, i.e. >90 % of the pores is
within the interval of 0.4-0.7 µm with a mean pore size of 0.6 µm,
whereas <3 % of the total pore volume is within the interval 10-50 µm.

Example 3

To a silicon raw material comprising a silicon powder called Sicomill 4D methyl alcohol is added. Subsequent to a careful rumbling grains larger than 5 μm are separated through a sedimentation. Thus, the remaining silicon raw material comprises powders with grain sizes <5 μm . A raw compact with the dimensions 10 x 5 x 30 mm is made through a cold isostatic pressing with 3 percent by volume polyethylene glycol as a lubricant. The evaporation of PEG is done through a heating with about 10°C/hour up to 400°C. Subsequently the raw compact is nitridized with a nitrogen gas containing atmosphere in two steps at 1160°C for 5 h and at 1400°C for 15 h, a reaction bound silicon nitride, Si_3N_4 (RBSN) being obtained. The nitridized specimen has a 22 percent by volume open (communicating) porosity, measured through a vacuum suction and a water penetration. Hg-porosimetry shows a very narrow pore size distribution with >90 % of the total pore volume in the interval of 0.2-1.0 μm and with <3 % in the interval of 10-50 μm . As to the pores in the interval of 0.2-1.0 μm the main part is more exactly within the interval of 0.2-0.4 μm .

Example 4

10 percent by volume glass fibers, made of CaAl-silicates, cemented to a diameter of 150 μm and having a length of 1-2 mm are added to a silicon nitride raw material called UBE E10. The mixture is homogenized and raw compacts are made in the same way as in Example 1. Specimens are made through a sintering of the raw compacts at 1800°C for 2 h in a nitrogen gas atmosphere in a powder bed of coarse silicon nitride. The total porosity of the specimens is measured through a water penetration to 11 percent by volume. An optical examination in a light microscope shows a coarse fraction of pores having a size of about 150 μm .

Example 5

From plates, made of completely dense silicon nitride, containing 2 % yttrium oxide and having a density of 3.22 g/mm³, made through a hot isostatic pressing at 1750°C, 160 MPa, 1 hour, 20 rod specimens are made, with the dimensions 3.5 x 4.5 x 40 mm, designed for a strength

testing, through a cutting and an edge breaking (45°). Half the amount of the rod specimens are provided with macropores on one side thereof through a computer controlled laser cutting, which gives a pore profile, which is shown schematically in Fig. 5. Strength measurements show that with pores having a depth of 200 μm and a profile according to Fig. 5 a lowering of the mean strength is obtained, determined through a 4-point bending test, from 680 MPa (without macropores) to 350 MPa. The mean value 350 indicates that the Y-value in the equation (1) is low. With a measured rupture strength value of 5.0 MPa $\text{m}^{1/2}$ this corresponds to an Y-value of about 1.2.

Example 6

Raw compacts from Example 3 are provided with surface macropores having a size of about 200 μm , obtained by treating the surface with a stamp having densely distributed outwardly projecting nails, called a "nail mat". The nails have a central distance of 400 μm and produce an impression with a depth of 200 μm . The profile of the impressions is shown in Fig. 7. Subsequently the specimens are nitridized in the same way as in Example 3.

The mean strength of the material, without surface macropores, which is made according to Example 3, determined through a 4-point bending test, is 290 MPa. A material with surface macropores, made according to Example 1, has a strength of 150 MPa, determined according to the same 4-point bending test.

Example 7

This example relates to a method of producing the material according to the invention. Specimens consisting of sintered zirconium oxide with 3 percent by volume yttrium oxide and having a density of 6.07 g/cm³ are surface treated with ultrasound, a boron carbide slurry/slamma with a grain size of about 30 μm being used. Ultrasound tools with varying topography, which corresponds to pore configurations according to Figs. 4 and 6, are used.

Example 8

This example shows a few feasible applications for the invention. A computer-controlled laser cutting can be used for the production of surface macropores on three implant components within areas, which when the implant is used are subjected to a low mechanical stress. The material within these areas consists of porous materials according to the invention and has been shaded in Figs. 1-3. These components are:

- a shoulder joint component, Fig. 1;
- a hip joint component (main, stem), Fig. 2; and
- a dental implant, Fig. 3.

The remaining parts of the implants, i.e. the non-shaded, more highly stressed portions, can consist of materials, which are more conventional implant materials, or also of other unconventional materials, which meet the specific requirements for these parts of the respective implant.

Example 9

Cylinders with a diameter of 2.8 mm and a length of 7 mm are produced from materials with surface macropores, described in Examples 3, 5, 6 and 7. These cylinders are inserted in a thigh bone in a rabbit. After three months the animals are killed and the necessary transverse forces for a discharge of the cylinders are determined with a so called push-out test. The results are compiled in Table 1:

25 Table 1

Material	Transverse force (MPa)			Remarks	
RBSN (Example 3)	2	No surface macro pores			
RBSN (Example 6)	11	With	"	"	"
Zirconium oxide (Example 7, pore appearance Fig. 4)	12	With	"	"	"
Silicon nitride (Example 5)	10	With	"	"	"
Silicon nitride (ref.-material)	2	No	"	"	"

Example 10

Cylinders with a diameter of 2.8 mm and a length of 7 mm, made of a material according to Example 2, i.e. consisting of a finely porous aluminum oxide, are surface treated through a laser process according to Example 5 in order to produce complex pore size distributions, namely a microporous fraction in the entire material, obtained when the cylinders are produced, and a macroporous surface fraction. The configuration of the surface macropores corresponds to what is shown in Fig. 5. In the open fine pore-structure Ca-phosphate is precipitated by reaction between calcium hydroxide and ammonium phosphate. In a similar way other bone growth stimulating agents can be added to the fine pore-structure, e.g. a bone growth factor or anti-inflammatory agents, e.g. through a freeze dehydration process. Cylinders, which are produced and treated in this way, are implanted in a thigh bone in rabbits. The animals are killed after 2, 5 and 8 weeks. Reference material without any Ca-phosphate deposit. The transverse forces between an implant and a new growth of bone is determined by a push-out testing. The results are shown in Fig. 8, which shows the transverse force as a function of the ingrowth time (weeks).

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CLAIMS

1. An implant made of a porous, non-toxic material with a total open porosity larger than 5 percent by volume but not larger than 80 percent by volume within at least a portion of the implant, characterized in that:
- communicating pores with a pore size within the interval of 0.1-10 μm occupy 10-80 percent of the total pore volume in said at least one portion of the implant;
 - pores with a pore size within the interval of 10-50 μm occupy not more than 5 % of the total pore volume in said at least one portion of the implant; and
 - 5-40 % of at least one portion of the surface of the implant is covered by mainly evenly distributed pores having a pore size within the interval of 50-500 μm .
2. An implant according to claim 1, characterized in that said communicating pores with a pore size within the interval of 0.1-10 μm occupy 25-75 %, suitably 40-60 %, of the total pore volume in said at least one portion of the implant material.
3. An implant according to claims 1 or 2, characterized in that said communicating pores have a pore size within the interval of 0.3-8 μm , suitably within the interval of 0.5-5 μm .
4. An implant according to claim 1, characterized in that 10-30 %, suitably 15-25 % of the surface within said at least one portion of the implant is covered by the pores having a pore size within the interval of 50-500 μm , which pores mainly are evenly distributed over the surface of said portion.
5. An implant according to claims 1 or 4, characterized in that the main part of the large pores in the surface layer have a size within the range of 75-400 μm , preferably within the range of 100-300 μm and suitably within the interval of 150-250 μm .

6. An implant according to any of claims 1, 4 and 5, c h a r a c t e -
r i z e d in that the large pores only are present in a surface
layer, which has a thickness of 3 mm, preferably 2 mm and suitably
0.3 mm.

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7. An implant according to any of claims 1-6, c h a r a c t e -
r i z e d in that 10-80 % of the total pore volume is occupied by the
larger pores having a pore size within the interval of 50-500 μ m.

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8. An implant according to any of claims 1-7, c h a r a c t e -
r i z e d in that said at least one portion of the implant mainly
consists of a reaction bound silicon nitride.

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9. An implant according to any of claims 1-7, c h a r a c t e -
r i z e d in that said at least one portion of the implant mainly
consists of one or several of calcium phosphate materials, titanium,
SiC, CrO_2 , chromium, cobalt-steels, high-alloyed stainless steels and
polymers.

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10. An implant according to any of claims 1-9, c h a r a c t e -
r i z e d in that said communicating pores with the smaller pore size
contain deposited substances, having desirable medical and/or biolo-
gical functions.

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1/3

Fig. 1.

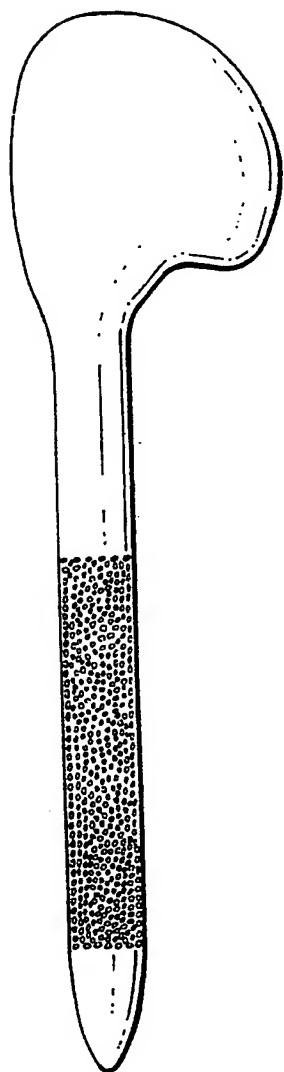


Fig. 2.

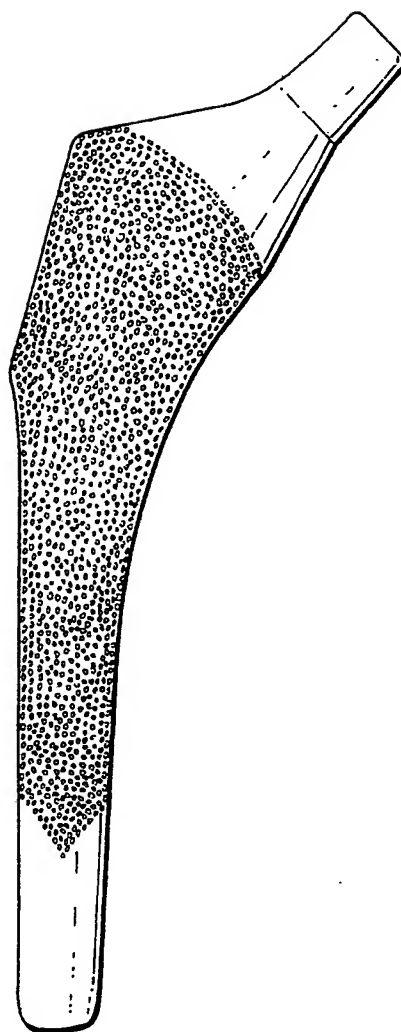


Fig. 3.



2/3

Fig. 4.

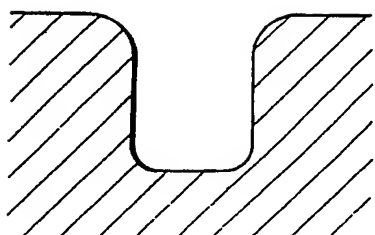


Fig. 5.

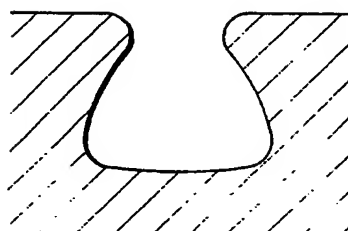
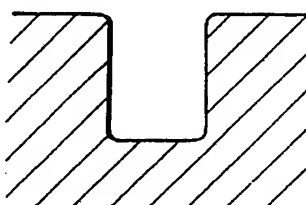


Fig. 6.



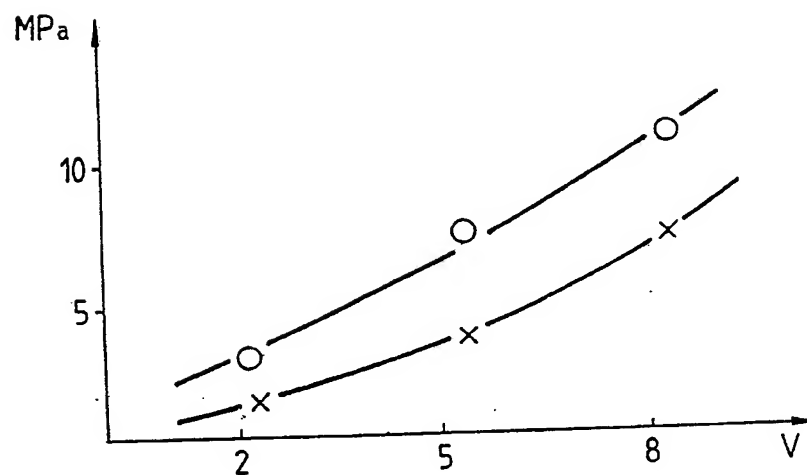
Fig. 7.



3/3

Fig.8.

—○— with deposited Ca-phosphate
—x— without deposited Ca-phosphate



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 92/00366

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 F 2/02, A 61 L 27/00														
II. FIELDS SEARCHED <div style="text-align: center; border: 1px solid black; padding: 2px;">Minimum Documentation Searched⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%; border: 1px solid black; padding: 2px;">Classification System</th> <th style="border: 1px solid black; padding: 2px;">Classification Symbols</th> </tr> <tr> <td style="border: 1px solid black; padding: 5px; vertical-align: top;">IPC5</td> <td style="border: 1px solid black; padding: 5px; vertical-align: top;">A 61 L; A 61 F</td> </tr> </table> <p style="text-align: center; font-size: small;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched⁸</p> <p>SE,DK,FI,NO classes as above</p>			Classification System	Classification Symbols	IPC5	A 61 L; A 61 F								
Classification System	Classification Symbols													
IPC5	A 61 L; A 61 F													
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; padding: 2px;">Category *</th> <th style="width: 60%; padding: 2px;">Citation of Document,¹¹ with indication, where appropriate, of the relevant passages¹²</th> <th style="width: 30%; padding: 2px;">Relevant to Claim No.¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4550448 (ROBERT V. KENNA) 5 November 1985, see the whole document ---</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-10</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">Dialog Information Services, File 351, (World Patent Index)81-92, Dialog accession no. 004824738, WPI Acc No. 86-328079/50, (AGEN) AGENCY O F IND SCI TECH), "Ceramic material for artificial bone etc. by sintering base material packing soln. and solidifying packed material", JP 61242978, A, 861029, 8650 (Basic) ---</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-10</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4834756 (ROBERT V. KENNA) 30 May 1989, see the whole document ---</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-10</td> </tr> </tbody> </table>			Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	A	US, A, 4550448 (ROBERT V. KENNA) 5 November 1985, see the whole document ---	1-10	A	Dialog Information Services, File 351, (World Patent Index)81-92, Dialog accession no. 004824738, WPI Acc No. 86-328079/50, (AGEN) AGENCY O F IND SCI TECH), "Ceramic material for artificial bone etc. by sintering base material packing soln. and solidifying packed material", JP 61242978, A, 861029, 8650 (Basic) ---	1-10	A	US, A, 4834756 (ROBERT V. KENNA) 30 May 1989, see the whole document ---	1-10
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<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>														
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border: 1px solid black; padding: 5px;"> Date of the Actual Completion of the International Search 8th September 1992 </td> <td style="width: 50%; border: 1px solid black; padding: 5px;"> Date of Mailing of this International Search Report 1992-09-14 </td> </tr> <tr> <td style="border: 1px solid black; padding: 5px;"> International Searching Authority SWEDISH PATENT OFFICE </td> <td style="border: 1px solid black; padding: 5px;"> Signature of Authorized Officer Sofia Nicolopoulou </td> </tr> </table>			Date of the Actual Completion of the International Search 8th September 1992	Date of Mailing of this International Search Report 1992-09-14	International Searching Authority SWEDISH PATENT OFFICE	Signature of Authorized Officer Sofia Nicolopoulou								
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	<p>US, A, 4654314 (SHIGEHIDE TAKAGI ET AL.) 31 March 1987, see the whole document</p> <p>--</p> <p>-----</p>	1-10

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.PCT/SE 92/00366**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 31/07/92. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US-A- 4834756	89-05-30
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